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as
Claim 17. (newly added) A method in accordance with Claim 14 wherein said method comprises utilizing linear changes in the signal path length so that the velocity path component is constant and the observed variance is from a velocity change of the sample component.

Sub 1
Claim 18. (newly added) A method in accordance with Claim 14 wherein the neovascular flow is determined by linear changes in the path length of a signal generated by the interferometric system.

REMARKS

In an embodiment, applicants invented an apparatus for guiding a guide wire through body tissue which comprises an interferometric guidance system coupled to the guide wire, the interferometric guidance system configured to detect neovascular flow through the tissue. In one aspect, the claimed apparatus is useful for providing passage through totally occluded blood vessels and is thus useful in the treatment of cardiovascular heart disease. In one embodiment, applicants invented an apparatus for detecting neovascular flow through an obstruction in a blood vessel, said apparatus comprising: an interferometric apparatus; a broad band filter coupled to an output of the interferometric apparatus, said interferometric apparatus generating interferometric peaks of varying frequencies; and a frequency-to-voltage converter coupled in series to said broad band filter. In another embodiment applicants invented a method to determine neovascular flow through tissue in a vessel, said method comprising the step of performing a Doppler shift analysis on frequencies of interference peaks generated by an interferometric system examining the vessel.

Heart disease and stroke are rampant in the U.S. Each year about one million Americans have heart attacks and about 500,000 die as a result. According to the American Heart Association, heart disease is the number one killer of Americans. Stroke is said to be the number three killer of Americans.

Clogged arteries – atherosclerosis – is a type of arteriosclerosis or the thickening and hardening of the arteries. This slow, progressive disease involves deposits of fatty

substances, cholesterol, cellular waste products, calcium and fibrin in the inner lining of the artery. This is called plaque. Plaque may totally or partially block the blood flow through the artery. This blockage, with or without a blood clot, may cause a heart attack or stroke by stopping the blood flow to the areas of the body that are supplied by these vessels. Even with techniques such as angioplasty, open heart surgery, atherorectomy, carotid endarterectomy, and stents, there remains the formidable obstacle of total occlusions which, are useful on partially occluded arteries.

The main concern with a total occlusion is that physicians cannot negotiate the guide wire of a catheter through a total occlusion without a substantial risk of perforating or damaging the blood vessel. This claimed invention addresses this concern and provides a solution as a viable alternative to bypass operations using this minimally invasive novel technology. The objective of the claimed invention is to guide a device through a total occlusion by sensing flow through a neovascular channel and successfully guiding a device through that neovascular channel. The claimed invention provides real-time feedback as to the proximity of the crossing wire to the arterial wall, facilitating safe and successful passage through total occlusions and placement of therapeutic catheters for recanalization in native coronary arteries.

Claims 1-18 are pending in the application. Claims 1-16 stand rejected as described below. Claims 17 and 18 are newly added. Also enclosed herewith is a Submission of Marked Up Claims in accordance with 37 C.F.R. § 1.121(c)(1)(ii).

Claims 1-16 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 2, 7, 11, 12, 14 and 15 have been amended in this regard. Thus, the rejection is moot and should be withdrawn.

Claim 1 has been amended at line one thereof to provide a positive antecedent basis for "the guide wire". Support for this amending is provided at page 2, lines 29-32 of the

specification. Claim 1 has also been amended at line 1 thereof to provide an antecedent basis for “said second end of said guide wire”. Support for this amending is provided at page 2, lines 29-32 of the specification.

Claim 7 has been amended at line 2 thereof to provide antecedent basis for “said first optic fiber” and “said second optic fiber”. Support for this amending is provided at page 2, lines 29-32; and page 3, lines 1-4 of the specification.

Claims 8-10 depend directly or indirectly on Claim 7 and according antecedent basis is now present for “said first optic fiber” and “said second optic fiber”.

Claim 11 has been amended on line 3 thereof whereby the phrase “the interferometric information” has been replaced with the phrase “the interference information” so that the claim is more technically correct. No new matter is presented by this amending in that support for this amending is provided at page 5, lines 13-15 of the specification.

Claim 12 has been amended on line one thereof so that the phrase “said interferometric apparatus” now has a positive antecedent basis. No new matter is presented by this amending in that support for this amending is provided at page 5, lines 13-15 of the specification.

Claim 14 has been amended on lines 2 and 3 thereof so the desired result to be achieved by the step of “performing a Doppler shift analysis” is now clear and definite. Any vagueness and indefiniteness, if originally present, is now cured. No new matter is presented by this amending in that support for this amending is provided at page 10, lines 1-5 of the specification.

The Examiner asserted that in Claim 2, the term “said second end of said guide wire” lacked antecedent basis. Claim 1 has been amended to provide that basis. Claim 2 depends on Claim 1 and any 112 defect, if originally present, is thereby cured.

Claims 17 and 18 are newly added. No new matter is presented in this amending in that support is found throughout the specification, particularly at page 12, lines 12-31 Examination of claims 17 and 18 is requested.

No new matter is presented by the above amending of Claims 1, 7, 11, 12, 14 and 15 and addition of Claims 17 and 18 in that support is provided in each instance and has been shown above. Withdrawal of the Examiner's rejection of Claims 1-16 based on 35 U.S.C. 112, paragraph 2, is requested.

The Examiner is thanked for the time and courtesy extended to applicants attorney and Mr. John Neet during the phone interview on April 30, 2002.

Illustratively, applicants independent claim 1 reads: Apparatus for guiding a guide wire through body tissue, said apparatus comprising at least one interferometric guidance system coupled to the guide wire, said interferometric guidance system for generating interference information from the body tissue, said interferometric system comprising a circuit for generating Doppler shift information to detect neovascular flow through the tissue.

Claims 1-4 and 7-11 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Tearney et al. This rejection is respectfully traversed along with the Examiner's reasoning. Tearney et al. is an imaging system as whereas the claimed invention is an apparatus configured for guiding a guide wire wherein at least one interferometric guidance system is coupled to a guide wire of applicants invention. (emphasis added). Applicants submit that Tearney et al. does not teach or suggest applicants' guidance apparatus, but rather Tearney et al. discloses an apparatus for imaging. Applicants' apparatus is patentably distinct over Tearney et al. Tearney et al fails to teach or suggest a system for guiding a guide wire and in particular a system having an interferometric system comprising a circuit for generating Doppler shift information configured to detect neovascular flow through the tissue. Thus, this rejection is overcome and should be withdrawn. While Tearney et al. mentions imaging

several times in that patent, applicants submit that Tearney et al. fails to teach or suggest a guidance system claimed by applicants.

Claims 2-3 and 4-7 depend, directly or indirectly, from independent Claim 1. When the recitations of Claims 2-3 and 4-7 are considered in combination with the recitations of Claim 1, applicants submit those dependent Claims 2-3 and 4-7 likewise is patentable over Tearney et al. The rejection of these Claims is overcome and should be withdrawn.

Claims 14-16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Swanson et al. This rejection is respectfully traversed along with the Examiner's reasoning.

1,2 Swanson et al. discloses a method of imaging and scanning and obtaining information. In contrast Applicants' invention is a guidance apparatus (emphasis added). Further applicants' claimed invention is configured to guide a guide wire and is configured to detect neovascular flow in tissue, both of which are absent in Swanson et al. (emphasis added). Thus, applicants Claim 14 (and applicants all other claims including newly added claims 17 and 18) are patentable over Swanson et al. ✓

Further, Swanson et al. describes a method to compensate for varying Doppler shift induced by the method that is used to change the optical path length in their device. In the previous paragraph to the citing (look at column 9, line 1), they describe a sinusoidal motion of mirror 32. The Doppler shift is directly proportional to a change in velocity ($2V/\lambda$) and since the motion is sinusoidal, the velocity varies as a sine function. What is being described in Swanson is a method to adjust the demodulator component to compensate for this varying Doppler shift caused by the sinusoidal velocity component. Applicant wishes to emphasize that the instant application provides a method to measure the velocity component of the sample, not to compensate for a varying velocity component in the reference. (The present invention uses linear changes in the path length so that the velocity component of path length change is constant and thus the observed variance is from the velocity change of

the sample component.) Thus the claimed invention is patentable over Swanson. Thus, this rejection is overcome and should be withdrawn.

Claims 15-16 depend directly or indirectly from Claim 14. When the recitations of Claims 15-16 are considered in combination with the recitations of Claim 14, applicants submit that Claims 15-16 are likewise patentable over Swanson et al.

Claims 5, 6, 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tearney et al. in view of Peterson et al. This rejection is respectfully traversed in its entirety along with its reasoning.

Applicants claimed invention is patentably distinct over Tearney et al. as applicants above remarks have already shown. There is nothing in Tearney et al. which, teaches or suggests the claimed invention or provides any motivation to change or modify Tearney et al. There is no suggestion in Tearney et al. to change, modify, what to change or if Tearney et al. were somehow changed for some reason that any resulting beneficial embodiment would occur.

Peterson et al. (U.S. Patent No. 5,549,114) discloses an apparatus for performing Doppler blood flow studies wherein processing circuitry includes a frequency-to-voltage converter. However, Peterson et al. does not teach or suggest applicants' claimed invention in particular applicants' apparatus which is configured to guide a guide wire and configured to detect neovascular flow in tissue. Thus the instant invention is patentably distinct over Peterson et al. as the above discussion shows.

4 The Examiner has somehow combined Tearney et al. with Peterson et al. This combination is not permissible. There is nothing in either Tearney et al. or Peterson et al., which would motivate or provide a reason (nor has the Examiner provided a sustainable reason) for somehow combining these two patents. Thus, the Examiner's combination cannot be sustained and should be withdrawn.

Applicants respectfully submit that it would not be obvious to one skilled in the art to combine Tearney et al with Peterson et al because there is no motivation to combine the references suggested in either Tearney et al or Peterson et al. As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d (Bd. Pat. App. & Inter. 1993) MPEP 2143.01. Rather there must be some suggestions, outside of applicants' disclosure in the art to combine such references. See in re Vaack, 20 U.S.P.Q. 2d '1435 (Fed. Ct. 1991). Applicants submit that the office action fails to provide any prior art references that suggest adding together elements of the instant claims. Thus the combination of Tearney et al and Peterson et al is overcome and should be withdrawn.

Additionally, the impermissible combination of Tearney et al. with Peterson et al. fails to teach or suggest the claimed invention in that applicants' apparatus is a guidance apparatus configured to guide a guide wire and configured to detect neovascular flow. Tearney et al., Peterson et al., and Tearney et al. with Peterson et al. fail to teach or suggest applicants' claimed invention specifically that applicants apparatus is a guidance apparatus in that it has at least one interferometric guidance system coupled to a guide wire. Thus, this rejection is overcome and should be withdrawn.

The patentable distinction of applicants invention is clear in that it comes down to Tearney et al's imaging versus applicants' guidance. Applicants guide their device through an occlusion by sensing flow and following the neo-vascular channel through an occlusion.

Applicant's capability of guiding through a neo-vascular channel in a total occlusion is a significant technology advance. Neither Tearney et al. nor Swanson nor Peterson are seen to teach or suggest the existence of the problem of total occlusions let alone provide a solution thereto as applicants claimed invention provides. Tearney et al. teaches devices that are scanning systems that look sideways or conically. Applicants have invented ways to guide the procedure with a fixed fiber that allows applicants' device to operate in real time to guide the procedure and to maintain low profile devices that can actually be used in interventional

plg. what is not claimed?

procedures. In particular, Tearney et al. clearly does not teach or suggest the invention concept recited in Claims 7 and 8 which calls for the fixed position.

It is believed that the amendments to the claims and the above remarks place the application in condition for allowance, and such favorable action is requested. Early allowance is requested.

In another embodiment of the invention, applicants independent Claim 12 reads: Apparatus for detecting neovascular flow through an obstruction a blood vessel, said apparatus comprising:

a broad filter coupled to an output of an interferometric apparatus, said interferometric apparatus generating interferometric peaks of varying frequencies; and

a frequency-to-voltage converter coupled in series to said board band filter.

In another embodiment, applicants' independent claim 14 reads: A method of determining neovascular flow in a vessel, said method comprising the step of performing a Doppler shift analysis on frequencies of interference peaks generated by an interferometric system examining the vessel.

Independent Claims 12 and 14 are patentably distinct over the references respectively cited by the Examiner for at least the reasons put forth by applicant above setting forth the patentability of independent Claim 1 and of the other claims.

Dependent claim 17 has been added and depends on claim 14. Claim 17 recites an embodiment of the invention for determining neovascular flow which comprises ... wherein said method comprises utilizing linear changes in the signal path length so that the velocity path component is constant and the observed variance is from a velocity change of the sample component. Claim 17 is patentably distinct over the cited references as none of the references teach or suggest this claimed embodiment. Dependent claim 18 has been added

and depends on claim 14. Claim 18 is patentably distinct over the cited references as none of the references teach or suggest this claimed embodiment.

Independent Claims 1, 12 and 14 (and newly added Claims 17 and 18) have been shown to be patentable. When the recitations in the dependent claims are considered in combination with their corresponding independent claims, applicant submits that all dependent claims likewise are patentable.

The patentability of each dependent claim on its own merits is respectfully requested since each dependent claim is also deemed to define an additional aspect of the invention requiring consideration or reconsideration, as the case may be.

All pending claims are patentable for at least the reasons put forth by applicants above. The elements called for in the pending claims are not taught or suggested in the references asserted by the Examiner and thus all the independent and dependent claims are patentable.

In view of the foregoing remarks, all claims now active in this application are believed to be in condition for allowance. Reconsideration is requested along with early passage to issue. Favorable action and allowance are respectfully solicited.

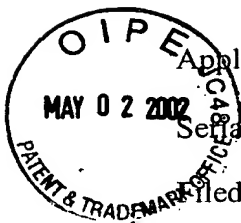
Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gordon F. Sieckmann", written over a horizontal line.

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#6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant: Thomas R. Winston, et al.

: Atty. Dkt. No.: 15225/41

Serial No.: 09/539,015

: Group Art Unit: 3737

Filed: March 30, 2000

: Examiner: S. Shaw

For: METHOD AND APPARATUS FOR
GUIDING A GUIDE WIRE

SUBMISSION OF MARKED UP SPECIFICATION AND CLAIMS

Assistant Commissioner for Patents
Box FEE-AMENDMENT
Washington, D.C. 20231

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TECHNOLOGY CENTER R3300

Sir:

Submitted herewith are marked up specification and claims in accordance with
37 C.F.R. § 1.121(c)(1)(ii).

IN THE SPECIFICATION:

On the first page after the title, "METHOD AND APPARATUS FOR GUIDING A
GUIDE WIRE" and before the Background of the Invention: This application is a
continuation in part of USSN 09/060,487 filed April 15, 1998 which is a continuation in part
of USSN 08/943,386 filed October 3, 1997 now US patent 5,951,482.

IN THE CLAIMS:

1. (once amended) Apparatus [for guiding] configured to guide a guide wire
a neovascular channel in
through body tissue, said apparatus comprising a guide wire having a first and second end
with at least one interferometric guidance system coupled thereto [to the] a guide wire; said
interferometric guidance system *for* generating interference information from the body tissue,
wherein said interferometric system [comprising] *further* comprises a circuit *configured to* for generating Doppler
and shift information configured to detect neovascular flow through the tissue. *How??*
indicating

7. (once amended) Guide wire guiding apparatus in accordance with Claim 1,
wherein said interferometric system further comprises a first optic fiber having a first end and
a second end;

*Means for detecting flow
neo. using doppler
info.*

a second optic fiber having a first end and a second end, wherein
said first optic fiber second end is polished at an angle of about 8 degrees relative to a
cross-sectional plane orthonormal to a long axis of said first optic fiber.

11. (once amended) Guide wire guiding apparatus in accordance with Claim 1
further comprising a visual graphic display coupled to said interferometric system, said visual
graphic display configured to display the [interferometric] interference information and the
Doppler shift information.

~~Function~~ 12. (once amended) Apparatus for detecting neovascular flow through an
obstruction in a blood vessel, said apparatus comprising: an interferometric apparatus,

a broad band filter coupled to an output of an said interferometric apparatus, said
interferometric apparatus generating interferometric peaks of varying frequencies; and

a frequency-to-voltage converter coupled in series to said broad band filter; and

means for performing a Doppler shift analysis on the data
14. (once amended) A method [for determining] to determine neovascular flow

through tissue in a vessel, said method comprising the step of performing a Doppler shift
analysis on frequencies of interference peaks generated by an interferometric system
examining the vessel. - *Incomplete*

15. (once amended) A method in accordance with Claim 14 wherein performing
the Doppler shift analysis includes the steps of:

- applying a known amplitude-modulated voltage signal to a first [PZT] piezo electric
transducer and a second [PZT] piezo electric transducer to produce a first known component
of a Doppler frequency shift in the frequencies of interference peaks;

measuring an actual Doppler frequency shift in the interference peaks;

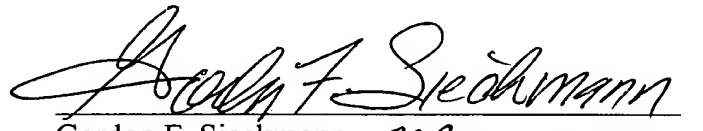
subtracting the first known component of the Doppler frequency shift from the actual
Doppler frequency shift to determine a second component of the actual Doppler frequency
shift, wherein the second component reveals the presence of neovascular channels in the
vessel.

Kindly add Claims 17 and 18 as:

--Claim 17. A method in accordance with Claim 14 wherein said method comprises utilizing linear changes in the signal path length so that the velocity path component is constant and the observed variance is from a velocity change of the sample component.- -

- - Claim 18. A method in accordance with Claim 14 wherein the neovascular flow is determined by linear changes in the path length of a signal generated by the interferometric system.- -

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MAY 2, 2002